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09/923,116	08/06/2001	William F. McKay	4002-2803	9548

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EXAMINER
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/923,116	MCKAY, WILLIAM F.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/16/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-47,49,52-56,58-60,62-64,68,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-47, 49, 52-56, 58-60, 62-64, 68 and 73-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-42, 48, 50-51, 57, 61, 65-67 and 69-72 are cancelled. Claims 73-74 are added. Claims 43-47, 49, 52-56, 58-60, 62-64, 68 and 73-74 are pending and under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claim 43, 45-47, 52, 60, 68 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al.,[1] and as evidenced by McKay, W.[2] .

In response to the rejection, Applicant submits that the composition of Chu et al. is not stable and flexible, as required by the claimed invention. To support's Applicant's position, Applicant directed the Office's attention to various sections of Chu et al.

This submission has been considered, however, it is not found to be persuasive. In the instant case, Chu et al. teaches both rigid and flexible compositions. Specifically, in Example 5 of Chu et al., Chu et al. teaches a composition that is molded into a desirable dimension prior to implantation. The ability of a composition of to be molded renders the composition flexible because it is able to take on any shape or molding.

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[1] Chu et al., U.S. Patent No. 4888366.
[2] McKay, W.F., U.S. Patent No. 5972368.

It is further noted that Applicant argues that Chu et al. teaches away from the claimed invention when Chu et al. notes that the rigid composition appeared to encourage bone formation more effectively than the material,made without air drying, the flexible composition.

This submission has been considered, however, it is not found persuasive. The comparative analysis provided by Chu et al. is not sufficient enough to demonstrate to one of ordinary skill in the art that he or she should limit his use to the rigid composition. In the instant case, while the flexible composition appears to not encourage bone formation any more effectively than the rigid composition, however, one of ordinary skill in the art, at the time the invention was made, would still be motivated to use the flexible composition because of the inherent advantages recognized for the composition, such as the ability to mold the flexible composition into any desirable dimension prior to implantation.

Additionally, it is noted that Applicant has amended the claims to contain additional language, including intended use and functional languages, such as “effective for the induction of new bone growth in a human” and “stimulate osteoclasts sufficiently to cause an increase in rate of resorption of said resorbable sponge matrix”.

The newly added language has been considered, however, it is determined that the additional language does not further limit the composition. In the instant case, the determination of patentability remains with the structural limitations recited in the claims, and not it’s intended use and functional characteristics, especially when such language does not further limit the claims. Moreover, MPEP § 2112(I) provides that “[T]he

discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Thus, while Applicant may have newly discovered the mechanism of action accorded by the composition of Chu et al., this discovery does not render the composition patentable over the composition of Chu et al.

The claims are directed toward an osteogenic composition comprising a stable and flexible device, wherein the device comprising of a resorbable sponge matrix formed of collagen and particulate biocompatible mineral embedded within the matrix, and an osteogenic factor. The claims require that the device comprises 1% to 3% by weight of collagen and 97% to 99% by weight of particulate biocompatible mineral. Independent claim 43 requires the collagen to be lyophilized. Claim 45, which depends on claim 43, limits the particulate biocompatible mineral to a synthetic ceramic, which is later limited to calcium phosphate by claim 46; which is further limited to biphasic calcium phosphate by claim 47. Claim 52, which depends on claim 43, requires the collagen to be telopeptide collagen. Claim 68, which depends on claim 43, requires the collagen to be fibrillar collagen.

Chu et al. teaches an osteogenic composition comprising a stable and flexible device, wherein the device comprise of a resorbable sponge matrix formed of collagen and particulate biocompatible mineral embedded within the matrix, and an osteogenic factor. [Examples 2-3, columns 12-13] The particulate biocompatible mineral that Chu et al. teaches is biphasic calcium phosphate, which is a calcium phosphate, which is

also a synthetic ceramic. The collagen that Chu et al. teaches is a telopeptide collagen and fibrillar collagen. [Lines 29-40, column 7; Line 64, column 12, respectively]

In the instant, a small difference exists between the percent by weight of collagen and particulate biocompatible mineral used Chu et al. and those instantly claimed. The percent by weight of collagen and particulate biocompatible mineral used by Chu et al. is 10% and 87.5%, respectively. And the percent by weight of collagen and particulate biocompatible mineral instantly claimed is 1% to 3% and 97% to 99%, respectively. However, MPEP § 2144.05 [R-3] (II) (A) sets forth that, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Specifically, MPEP § 2144.05 [R-3] (II) (A) provides the following: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Thus, in view of the cited guidance provided in the MPEP, and in the absence of a disclosure citing that the claimed percent by weight of collagen and mineral is critical to the claimed invention, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use various percent by weight of collagen and mineral. The use of various percent by

weight of collagen and mineral is also acknowledged by Chu et al. Chu et al. suggests the use of about 2-40%, preferably 5%-25% by weight of collagen, and 60%-98% by weight of mineral. [Paragraph bridging columns 7-8] One of ordinary skill in the art at the time the invention was made would have been motivated to do so to determine the optimum or workable ranges. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the discovery or optimum or workable ranges is routinely practiced in the art.

It is noted that claims 43 and 45-47 require the collagen present be lyophilized collagen. In the instant, it is not readily apparent if the collagen used by Chu et al. is in lyophilized form. However, Chu et al. does recognize the use of the lyophilized form of collagen. [Lines 44-50, column 7] Chu further states that any non-reconstituted collagen preparation may be used. Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use the lyophilized form of collagen. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to provide mineral/collagen carrier for the composition of Chu et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the lyophilized form of collagen is recognized in the art as an alternative equivalent to the collagen used by Chu et al.

Additionally, it is noted that while claims 73-74 is directed toward a product, the cited claims also recite the method in which the product is made. However, MPEP § 2113 [R-1] provides the following: "[E]ven though product-by-process claims are limited

by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). MPEP § 2113 [R-1] further provides that the structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In the instant, the process steps recited in the claims has been evaluated, however, no particular structural characteristic can be rendered from the process steps. The claimed composition remains to be an osteogenic composition, which is obvious over the teachings of the art cited herein.

It is further noted that the claims require the device to be three dimensionally stable and flexible. In the instant, it is noted that the Chu et al. is silent on the flexibility of the composition. However, in the absence data available for direct comparison, the final basis of compositional equality is based on the ingredients and the proportions of the ingredients used in the composition. Applicant claims the use of 1% to 3% by weight of collagen. Chu et al. suggests the use of about 2-40%, preferably 5%-25% by weight of collagen. Applicant claims the use of 97% to 99% by weight of the particulate

biocompatible mineral. Chu et al. teaches 60% to 98% by weight of the particulate biocompatible mineral. In both instances, the range that Chu et al. teaches encompasses the range that is instantly claimed. Ergo, based on a comparative teaching between the instant disclosure and the disclosure of Chu et al. it is determined that the osteogenic compositions are the same. Any characteristics describing the claimed osteogenic composition would be inherent features in the osteogenic composition of Chu et al. because **the osteogenic compositions are indistinguishable**.

Furthermore, it is clearly evident from the teachings provided by Chu et al. that the composition of Chu et al. is flexible. Chu et al. teaches that compositions that contains a mixture of collagen and particulate biocompatible mineral cannot attain a modulus value that is much greater than 100 N/cm^2, wherein compressive modulus measures the resiliency of a composition. In the instant, Chu et al. teaches a composition has a compressive modulus above 20 N/cm^2, preferably 20-30N/cm^2. [Paragraph bridging columns 8-9.] The compressive modulus value for the composition of Chu et al. is well within the 100N/cm^2 threshold that is noted for such compositions. Thus, the composition of Chu et al. is resilient. Thus, the composition of Chu et al. is flexible.

Moreover, while Chu et al. is silent on the flexibility of the composition, however, it is well known in the art that the addition of collagen to a mineral based composition renders a composition elastic, as evidenced by McKay, W. McKay, W. teaches that the presence of collagen and mineral results in a composition that has elasticity that is

similar to bone. [Lines 7-12, column 18.] In the instant case, the composition of Chu et al. contains collagen. Hence, the composition of Chu et al. is resilient and has elastic activity. Thus, the composition of Chu et al. is flexible.

Additionally, it should be noted that the composition of Chu et al. is flexible. In Example 5 of Chu et al., Chu et al. teaches that the composition can be molded into a desirable dimension prior to implantation. The ability of a composition of to be molded renders the composition flexible enough to take on any shape or mold.

4. Claims 43-44 and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366, as applied to claim 43; in view of Geistlich et al.[3]

In response to the rejection, Applicant amended the claims, and submits that the composition of Chu et al. is not flexible and that Chu et al. teaches away from the claimed composition.

This submission has been considered, however, it is not found persuasive for the same reason(s) provided in paragraph 4 of this office action.

Claim 44, which depends on claim 43, limits the particulate biocompatible mineral to bone particles. Claim 56, which depends on claim 43, requires the particulate biocompatible mineral to have an average particle diameter of at least .5 mm. Claim 58, which depends on claim 43, requires the particulate biocompatible mineral to have an average particle diameter of about .5 mm to about 5 mm, which is later limited to about 1mm to about 3mm by claim 59.

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[3] Geistlich et al., U.S. Patent No. 5,573,771.

The significance of Chu et al., as it pertains to claim 43, is provided above. The particulate biocompatible mineral that Chu et al. teaches is synthetic calcium phosphates. Chu et al. used the synthetic calcium phosphates instead of bone particles.

Geistlich et al. teaches the use of bone particles as the particulate biocompatible mineral. Geistlich et al. teaches that bone particles are highly biocompatible prosthetic bone replacement. Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use bone particles as the particulate biocompatible mineral. One of ordinary skill in the art at the time the invention was made would have been motivated to do so for prosthetic bone replacement. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because bone particles and synthetic calcium phosphates are functional alternatives of the other.

Additionally, it is not readily apparent what is the average particle size of the particulate biocompatible mineral used by Chu et al. Chu et al. simply teaches that any particle size can be used. [Lines 10-20, column 7.] In the instant, Geistlich et al. teaches that the following particle sizes can be used, 0.1 mm to 10 mm. [Line 67, column 4.] The range disclosed by Geistlich et al. encompasses the range claimed by Applicant. In the instant, the art recognizes the use of the claimed particle sizes. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any particle sizes. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to discover the optimal or

workable range. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because the determination of an optimal or workable range is routinely practiced in the art.

5. Claims 43, 52-55, 60 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., as applied to claims 43 and 52; in view of McKay, W.

In response to the rejection, Applicant amended the claims, and submits that the composition of Chu et al. is not flexible and that Chu et al. teaches away from the claimed composition.

This submission has been considered, however, it is not found persuasive for the same reason(s) provided in paragraph 4 of this office action.

The significance of Chu et al., as it pertains to claims 43 and 52, is provided above.

Claim 53, which depends on claim 52, which depends on claim 43, limits the osteogenic factor to bone morphogenic protein (BMP), which is later limited to BMP-2 by claims 54-55. Claims 62-64 recite the same limitation as claims 53-55 with the exception that claims 62-64 recite a dependency to claim 60.

Chu et al. also teaches the use of bone morphogenic proteins as the osteogenic factor. [Lines 50-52, column 5.] While Chu et al. does not specifically teach BMP-2, however, Chu et al. teaches that any sources of osteogenic factors can be used. In the instant, McKay, W. teaches BMP-2. Hence, at the time the invention was made, BMP-2 is known in the art. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use any sources of osteogenic

factor, including BMP-2. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to induce osteogenic growth. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because BMP-2 is a known osteogenic factor.

6. Claims 43 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., as applied to claim 43; in view of Michelson.[4]

In response to the rejection, Applicant amended the claims, and submits that the composition of Chu et al. is not flexible and that Chu et al. teaches away from the claimed composition.

This submission has been considered, however, it is not found persuasive for the same reason(s) provided in paragraph 4 of this office action.

Claim 49, which depends on claim 43, is directed toward an interbody spinal fusion device containing a load bearing member and the composition of claim 43.

The significance of Chu et al., as it pertains to claim 43, is provided above. Chu et al. does not teach an interbody spinal fusion device containing a load bearing member and the composition. As noted previously, Chu et al. teaches an osteogenic composition. However, Michelson teaches a spinal fusion implant device. Michelson suggests using the implant device to be filled with and hold any natural or artificial osteoconductive, osteoinductive or osteogenic material. (Line 20-27, column 3). Hence, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Michelson with Chu et al. One of

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[4] Michelson, U.S. Patent No. 5,785,710.

ordinary skill in the art at the time the invention was made would have been motivated to do so to facilitate spinal osteogenic growth. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for doing so because Chu et al. teaches an osteogenic composition and Michelson teaches a spinal implant device for use with the osteogenic composition of Chu et al.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bruce R. Campell/
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